

Amendments to the Drawings:

The attached sheets of drawings include changes to FIGS. 1 and 6. These sheets, which include FIGS. 1, 6 and 6A replace the original sheets including FIGS. 1, 6 and 6A.

Attachment: Replacement Sheets

REMARKS/ARGUMENTS

Claims 1 and 5-9 are pending. Withdrawn claims have been cancelled, not to avoid any reference but to further prosecution. The Applicant reserves the right to present the unamended claims in a continuing application. FIGS. 1 and 6 have been amended to address issues brought up by the Examiner. No new matter has been added with the amendment to the claims or figures. Reconsideration of this Application and entry of this Amendment after Final are respectfully requested. The proposed amendment places the claims in better form for appeal. Additionally, this amendment addresses items brought up by the examiner in the final office action. In view of the amendments and following remarks, favorable consideration and allowance of the application is respectfully requested.

Drawing Objections

The drawings were objected to for not including line B-B in FIG. 6. FIG. 6 has been amended to include this line. Line B-B was included in the original figure 6 filed on April 22, 2004 and inadvertently omitted from the subsequently filed formal figures. Thus no new matter has been added with this amendment. A Replacement sheet showing this amendment is attached.

The drawings were also objected to for not showing every feature of the invention specified in the claims, namely, an o-ring and a port including a lock. FIG. 1 has been amended to illustrate the o-ring within a leg of the Y-arm port as discussed at page 8 lines 4 to 7. Thus no new matter has been added with this amendment.

The withdrawn claims reciting the port including a lock have been cancelled by the present amendment, thereby obviating the objection.

For these reasons, the withdrawal of the objections to the figures is respectfully requested.

35 U.S.C. §112 Rejections

Claims 1, 5-9 and 21 were rejected under 35 USC §112, first paragraph, as failing to comply with the written description requirement. The Examiner rejected these claims alleging that the specification and drawings fail to show an o-ring having an o-ring diameter wherein a proximal portion of the sleeve is positioned proximal to the port vessel. This rejection is respectfully traversed.

To satisfy §112 first paragraph, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116. Much of the written description case law addresses whether the specification as originally filed supports claims not originally in the application. The issue raised in the cases is most often phrased as whether the original application provides "adequate support" for the claims at issue or whether the material added to the specification incorporates "new matter" in violation of §132. However, as noted below, the specification as filed clearly provides both the requisite "adequate support" as well as full actual support for the claim limitations added.

The original disclosure does, in fact, support the claim limitations of independent claim 1. The Examiner is reminded that §112 first paragraph only requires that the specification reasonably convey to one of ordinary skill in the relevant art that the inventor had possession of the claimed invention. Here, the Examiner has not provided any evidence to support any particular definition of the skill level, and Applicant asserts that one of ordinary skill in the art would find that the inventor had possession of the claimed invention at the time of filing based on the specification. First, for example, FIG. 1 and page 8, lines 4-7 clearly illustrate and describe that a proximal portion of the sleeve (10) is positioned proximal to the port vessel (60) as would be understood by one with ordinary skill in the art. Further, the Applicant submits that one of ordinary skill in the art would not require that an o-ring be illustrated in order to understand the

Applicant's invention. Regardless, in an effort to move along the prosecution of this application, the Applicant has amended FIG. 1 to include an o-ring as recited in the remaining pending claims. Claim 21 has been cancelled by the present amendment. For these reasons, the rejection of claims 1, 5-9 and 21 under §112, first paragraph is requested.

35 U.S.C. §102 Rejections

Claims 1, 5, 7 and 8 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,270,521 to Fischell et al., (the Fischell patent). The Applicant traverses this rejection.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the . . . claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Thus, to warrant this §102 rejection, the reference cited by the Examiner must show each and every limitation of the claims in complete detail. The Applicant respectfully asserts that the Fischell patent fails to include each and every element of the Applicant's invention as claimed, as required to maintain a rejection under 35 U.S.C. §102(b). See MPEP 2131.

The Applicant asserts that the Fischell patent fails to disclose, teach, or suggest a system including a catheter; a stent assembly coupled to the catheter; the stent assembly comprising a coated stent including a stent framework and a drug coating disposed on at least a portion of the stent framework, a protective sleeve removably covering the stent deployment assembly and at least a portion of the catheter, wherein said sleeve comprises a hollow tube having a proximal outer diameter, a medial inner diameter, and a distal inner diameter; and wherein the distal inner diameter is sufficient to encircle an outer diameter of the stent deployment assembly, and wherein the medial inner diameter is sufficient to encircle an outer diameter of the catheter, and wherein the distal inner diameter is open, wherein the protective sleeve is removed from covering the stent

framework prior to deploying the stent, and a port to a vessel, the port including an o-ring having an o-ring inner diameter, wherein a proximal portion of the sleeve is positioned proximal to the port vessel and wherein the outer diameter of the proximal portion is greater than the o-ring inner diameter, as recited in claim 1.

The Examiner alleges that Fischell teaches a system for treating a vascular condition comprising “a port to a vessel (18), the port including an o-ring having an o-ring inner diameter (portion of 18 acts as an o-ring), wherein a proximal portion of the sleeve (34) is positioned proximal to the port vessel and wherein the outer diameter of the proximal portion is greater than the o-ring inner diameter (Fig. 2c)” (see, Final Office Action, page 4).

However, FIG 2C of the Fischell patent illustrates an angioplasty catheter 20 having an angioplasty balloon 18 and a slidable sheath 30 having an ultra-thin section 34, the sheath coaxially situated about the balloon angioplasty catheter 20 (see col. 3 lines 58-63 and col. 4 lines 17-18 and 36-37). Nowhere within the Fischell patent does it teach that angioplasty balloon 18 comprises a port to a vessel as that term is understood by one with ordinary skill in the art and as claimed and described by the Applicant. Further, nowhere within the Fischell patent does it teach that angioplasty balloon 18 has a portion that “acts as an o-ring” as alleged by the Examiner. Furthermore, nowhere within the Fischell patent does it teach that a proximal portion of sleeve 34 is positioned proximal to a port vessel. In fact nowhere within the Fischell patent does it teach or suggest these limitations. For at least these reasons, the Fischell patent does not anticipate claim 1 or any claim depending therefrom.

Claims 5, 7 and 8 depend from claim 1 and include all of the limitations of that claim. Thus for at least this reason, claims 5, 7 and 8 are not anticipated by the Fischell patent. For these reasons, the withdrawal of the rejection of claims 1, 5, 7 and 8 under 35 U.S.C. § 102(b) is respectfully requested.

35 U.S.C. §103 Rejections

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references when combined must teach or suggest all the claim limitations. *See* MPEP 2143. To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). *See* MPEP 2143.03.

Further, the recent KSR decision mandates that these claims be found patentable over the prior art. *See, KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1734, 82 USPQ2d 1385, 1391 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including (1) the scope and content of the prior art, (2) any differences between the claimed subject matter and the prior art, (3) the level of skill in the art. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966). *See also KSR*, 127 S.Ct. at 1734, 82 USPQ2d at 1391 (“While the sequence of these questions might be reordered in any particular case, the [*Graham*] factors continue to define the inquiry that controls.”).

- A. Claim 6 has been rejected under 35 U.S.C. §103(a) as being unpatentable over the Fischell patent

The Applicant traverses this rejection. The Applicant respectfully asserts that the Roberts patent and Fischell patent, alone or in combination, fail to disclose, teach, or suggest all the claim limitations of dependent claim 6.

As noted above, the Fischell patent does not teach or suggest all of the claim limitations of claim 1. Specifically, the Fischell patent does not teach or suggest, at least, the port including an o-ring having an o-ring inner diameter, wherein a proximal portion

of the sleeve is positioned proximal to the port vessel and wherein the outer diameter of the proximal portion is greater than the o-ring inner diameter, as recited in claim 1.

Claim 6 depends from independent claim 1 and includes all the elements and limitations of that independent claim. The Applicant therefore respectfully submits that dependent claim 6 is allowable over the Fischell patent for at least the same reasons as set forth above with respect to independent claim 1.

The withdrawal of the rejection of claim 6 as being unpatentable over the Fischell patent is respectfully requested.

B. Claim 9 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Fischell in view of Roberts

As noted above, the Fischell patent does not teach or suggest all of the claim limitations of claim 1. Specifically, the Fischell patent does not teach or suggest, at least, the port including an o-ring having an o-ring inner diameter, wherein a proximal portion of the sleeve is positioned proximal to the port vessel and wherein the outer diameter of the proximal portion is greater than the o-ring inner diameter, as recited in claim 1. The Roberts patent does not cure this defect. At most, the Roberts patent teaches a sleeve having a proximal portion that has an outer diameter the same as the medial portion of the sleeve. Thus, Fischell in view of Roberts does not teach or suggest all of the claim limitations of independent claim 1.

Claim 9 depends from independent claim 1 and includes all the elements and limitations of that independent claim. The Applicant therefore respectfully submits that dependent claim 9 is allowable over Fischell in view of Roberts for at least the same reasons as set forth above with respect to independent claim 1.

The withdrawal of the rejection of claim 9 as being unpatentable over Fischell in view of Roberts is respectfully requested.

Conclusion

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (707) 543-5021.

Respectfully submitted,

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